UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,732	04/08/2004	Yasuyuki Kawashima	11333/38	1524
	7590 02/10/201 ER GILSON & LIONE	EXAMINER		
P.O. BOX 10395			SRIVASTAVA, KAILASH C	
CHICAGO, IL 60610			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			02/10/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)		
10/821,732	KAWASHIMA, YASUYUKI		
Examiner	Art Unit		
Kailash C. Srivastava	1657		

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 16 December 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires _____months from the mailing date of the final rejection. a) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The Notice of Appeal was filed on 16 December 2010. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: _____. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. 🔲 Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. 🔀 For purposes of appeal, the proposed amendment(s): a) 🔲 will not be entered, or b) 🔀 will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: NONE. Claim(s) objected to: NONE. Claim(s) rejected: 11,14-21,25 and 26. Claim(s) withdrawn from consideration: NONE. AFFIDAVIT OR OTHER EVIDENCE 8. 🗌 The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. 🗌 The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

<u>See continuation sheet.</u>

12. Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s).

13. Other: Attached hereto: annotated copy of proposed amendment to the Claims and amendment and response filed 12/06/2010

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657

- 1. Claim Status according to amendment filed 2/16/2010 is as follows:
- a. Claims 1-10, 12-13, 22-24 and 26 remain cancelled;
- b. Claims 11, 14, 16-18, 20-21 & 25-26 have currently been amended; and
- c. Claims 11, 14-21 & 25-26 are pending and under examination.
- 2. Regarding applicants' response to art based rejections:
- A. Claims 11, 14-17 and 25 are rejected under 35 U.S.C. §102(b) as anticipated by Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, Pages 4223–4231).

In response to the rejection supra, citing a 2010 posting from BD FACStar Plus Cell Sorter Flow Cytometer, Applicants argue that the Examiner–cited cell sorter could not be located and the currently presented Claims 11, 14-17 and 25 are not anticipated by Wallner et al (Response filed 12/16/2010 after the final Office Action, Page 5, Lines 20-30, Page 6, Lines 24-38 & Page 7, Lines 4-22). Please note, the Examiner-cited cell sorter was posted in 2002 and said reference is a supporting document to Wallner et al., reference. A supporting document to a cited reference is permissible in a 102 rejection and does not have to be a part of the reference per se.

First of all, the instantly claimed invention is an apparatus and is broadly interpreted as a composition. As long as the prior art reference teaches each and every component of the claimed composition as has been discussed at pages 3-5, items 9-10 of the Office Action with Final rejection mailed on 17 June 2010, the claimed invention is anticipated by the cited reference. The Wallner et al., reference with support from the 2002 posting for the BD FACStar Plus Cell Sorter Flow Cytometer, teaches the same components (i.e., sampling device, cell size detector, fluorescence detector, processor, memory, programs and displaying scattergrams) as are instantly claimed. The Examiner further asserts that the functional intended use describing language (e.g., obtaining a slope of maximum variance direction or creating a scattergram) in each of Claims 11, 14, 15, 18 as described in currently presented claims (e.g., processing samples or processing data to make a scattergram) are functional intended use of said components of the claimed apparatus and would not bring about any change to said components of the claimed apparatus and therefore do not carry any patentable weight. Furthermore, Wallner et al., teach an apparatus that measures bacteria, distinguishing different sizes of the bacteria and present the information obtained as a scattergram. Thus, the description in currently presented Claims 11, 14-17 and 25, despite presenting functional intended use of an apparatus has been evaluated and considered from the view point of as if said language was including a structural configuration of a device.

3. Claims 11, 14-15, 17, 19, and 25 are rejected under 35 U.S.C. §102(b) as anticipated by Fukuda et al (US Patent 6,165,740 A).

In response filed 16 December 2010 to above-cited Final rejection, Applicants assert that Fukuda et al., fail to disclose a bacteria measuring apparatus having same features as instantly claimed (Response filed after the final Office Action on 12/16/2010, Page 7, Lines 23-34). A further assertion has been made that while Fukuda et al., disclose a flow cytometer measuring particle size of microorganisms, assaying program determining first and second particle size distribution from scattered light, determining the difference in the 1st and 2nd particle size distributions, Fukuda et al., merely disclose a device that can distinguish among the several types of bacteria but does not include the equipment configured to perform the analysis recited in Claims 11 and 25 (Response filed on 12/16/2010 after the final Office Action, Page 7, Lines 33-34; Page 8, Lines 4-8).

As Applicants assert, Fukuda et al., teach the device as claimed in Applicants' instant invention. If said device is not comprised of the equipment in the same configuration, the device would not measure microbial particles, distinguish among several types of bacteria and further would not display the information obtained as a scattergram, which even though are functional intended use of Applicants' claimed apparatus, are as Applicants assert (See, Applicants' response filed on 12/16/2010 after the final Office Action, Page 7, Lines 33-34; Page 8, Lines 4-8) in Fukuda et al's teachings. Thus, Fukuda et al., anticipate the invention instantly claimed in Claims 11, 14-15, 17, 19, and 25.

4. Claims 11, 14-21 and 25-26 are rejected under 35 U.S.C. § 103(a) as obvious over combined teachings from Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, 223–4231) and Fukuda et al (US Patent 6,165,740, issued 26 Dec 2000) in view of Dow et al (1979. Particle size distribution analysis for the rapid detection of microbial infection of urine. Journal of Clinical Pathology, Volume 32, Pages 386-390).

Regarding Applicants' arguments to obviousness rejection of Claims 11, 14-21 and 25-26 under 35 U.S.C. § 103(a) over combined teachings from Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, 223–4231) and Fukuda et al (US Patent 6,165,740, issued 26 Dec 2000) in view of Dow et al (1979. Particle size distribution analysis for the rapid detection of microbial infection of urine. Journal of Clinical Pathology, Volume 32, Pages 386-390), Applicants arguments are that like the primary references, Dow et al., do not suggest or disclose bacteria measuring apparatus having processor and memory including program that obtain a maximum variance direction of distribution of the bacteria and a scattergram.

Please note, only the Wallner et al., is primary reference. As illustrated/discussed supra in items A-B, the component features of the apparatus claimed in instantly presented Claims 11, 14-21 and 25-26 are anticipated in teachings from each of Wallner et al., and Dow et al., reference substantiates Wallner et al's teachings of an apparatus comprising the components instantly claimed (i.e., sampling device, cell size detector, fluorescence detector, processor, memory, programs and displaying scattergrams). In addition to describing a probe (i.e., sampler), channelyzer (Cell size detector), a particle size distribution profile on an X-Y plotter (display) also teach a computer that analyzes the profiles. The computer would inherently be equipped with memory, programs, processor, operating systems to execute the programs and a display of results. According to Dow et al's teachings, the data analysis despite being the functional use of the device since it can analyze any type of data given the appropriate software is there; would intrinsically analyze the cell size distribution to get maximum variance direction of bacterial distribution because a scattergram is produced.

Continuation Sheet (PTO-303)

Application No.

Thus, the claimed invention in instantly presented Claims 11, 14-21 and 25-26 is both anticipated and obvious over Examiner-cited prior art references cited supra,

/Kailash C Srivastava/ Patent Examiner Art Unit 1657 (571) 272-0923